UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,030	02/03/1999	MICHAEL GERARD TOVEY	23164-1001-D	1869

1444 7590 08/03/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/243,030	TOVEY, MICHAEL GERARD	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed May 8, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 22-57 are currently pending and are the subject of this Office Action.

Terminal Disclaimer

The terminal disclaimer filed on May 8, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,361,769 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Upon further consideration, Claims 22-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 and 39 recite the limitation "in which the effective dose of interferon is administered..." in line 2 of each respective claim. There is insufficient antecedent basis for this limitation in the claims.

Claims 36, 37 and 52 recite the limitation "comprises administering to the mammal..." in line 2 of each respective claim. There is insufficient antecedent basis for this limitation in the claims. Claims dependent from claims 36, 37 and 52 carry forth this limitation and are thus also included in this rejection.

Claims 36 and 52 recite the limitation "...an effective amount of greater than about 20 x 10^6 IU of interferon..." in lines 3-4 of claim 36 and lines 4-5 of claim 52. This limitation is indefinite because the metes and bounds of the dose cannot be determined. "Greater than" implies a solid limit on the lower dose (*e.g.* 20 x 10^6 is not included, only doses above 20 x 10^6 are included). However, "about" removes the limit implied by "greater than" and the lowest dose is not clear (*i.e.* what are the metes and bounds of "about" in the instant claims?). Claims dependent from claims 36 and 52 carry forth this limitation and are thus also included in this rejection.

Similarly, claim 47 recites the limitation "from up to about 500 x 10^6 IU" in line 2. The limitation is indefinite because the metes and bounds of the dose cannot be determined. "From" implies a definite lower limit (in this case, 500 x 10^6 IU). However, "from about" removes this limitation and renders the claimed dosage indefinite.

Claims 36, 37 and 52 recite the limitation "said oromucosal administration" in lines 6-7 of claims 36 and 37 and lines 8 of claim 52. There is insufficient antecedent

basis for this limitation in the claims. Claims dependent from claims 36, 37 and 52 carry forth this limitation and are thus also included in this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-32, 36-52 and 56-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-15 of U.S. Patent No. 6,207,145 and claims 1-14 and 16 of U.S. Patent No. 5,997,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods for treating a neoplastic condition comprising administering interferon via oromucosal contact of the '145 and '858 patents render the instant methods obvious when the method is used to treat a neoplastic condition caused by a virus.[1]

Applicant's arguments have been fully considered but they are not persuasive for the following reasons. Applicants argue that:

> "One of ordinary skill in the art, aware that a particular medicament may be efficacious for the treatment of a neoplastic condition, would not consider it prima facie obvious that such a medication would be useful for the treatment of a viral infection." Applicant's arguments, May 8, 2006, page 3, second paragraph.

This argument is not persuasive because the '145 patent discloses an "interferon composition for oromucosal contact to stimulate host defense mechanisms or an immune response" (Abstract). One skilled in the art would appreciate that a method of stimulating a host defense mechanism or immune response would be an effective treatment for a viral infection. Further, the '145 patent discloses "a method for treating

[1] Examiner reminds applicants that the present rejection is only directed to claims drawn to the general treatment of any and all viral infections. Note that claims directed to specific viral infections are not included in this rejection.

autoimmune, myobacterial, and neurodegenerative diseases, neoplastic conditions and viral infections..." (column 3, lines 64-66). Thus, the skilled artisan, when presented with the '145 and '858 patents would be imbued with at least a reasonable expectation that treatment with the same methodology used to treat a neoplastic condition of viral origin would also be effective to treat viral infections in general. This is especially true considering Type-I interferon is has been used to induce "anti-viral, anti-antiproliferative and other immunomodulatory effects" ('145 patent, column 1, lines 29-31). Finally, the '145 patent demonstrates the effectiveness of oromucosal interferon against vesicular stomatitis virus (Example 4, col. 13, lines 33-55).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Examiner
AU 1614

July 25, 2006

8/1/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER